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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,070	07/10/2003	Matt Neville	FORS-08195	8224

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EXAMINER
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JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,070	<b>Applicant(s)</b> NEVILLE ET AL.	
	<b>Examiner</b> Diana B. Johannsen	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 16 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>part of 20060717</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0506</u> . | 6) <input type="checkbox"/> Other: _____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 11-17, in the reply filed on May 23, 2006 is acknowledged. It is noted that claims 15 and 17, as well as non-elected claims 1-10 and 18-24 have been canceled. Accordingly, only elected claims 11-14 and 16 are now pending and under consideration.
2. Applicants' traversal of the further restriction applied to Group II in the Restriction Requirement of February 23, 2006 is noted. The examiner concurs with applicants' representative that the requirement is now moot in view of the cancellation of claims 15 and 17. However, Applicants are advised that future claims directed, e.g., to any member of a group of multiple combinations of polymorphic sequences may necessitate an election of species requirement of the type discussed in the interview of May 26, 2006 (see Interview summary mailed June 2, 2006).

### ***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

### ***Specification***

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see, e.g., page 76). Applicant is required to

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delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The use of the trademarks QIAAMP, HERCULASE, and CYTOFLUOR has been noted in this application. The trademarks should be capitalized wherever they appear, and, if necessary, be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

### ***Drawings***

6. The drawings are objected to for the following reasons:

- a) Figures 1A and 1B (filed 12/23/2003), Figure 6 (original), and Figure 19 (original) contain text too small to be legible;
- b) There is a single Figure identified as Figure "4A" (i.e., there is no Figure 4B); further, the specification refers only to "Figure 4." Accordingly, the Figure now identified as "4A" should be identified as Figure "4."

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

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made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Information Disclosure Statement***

7. The information disclosure statement filed May 23, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It is noted that as copies of the following documents were not provided in either the instant application or in parent application 10/411,954, the references have not been considered: EP0463395; WO 03/00091.

***Claim Objections***

8. Claim 14 is objected to because of the following informalities: the claim recites "the copy of number" rather than "the copy number" (see line 2). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "said exposure step" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. This rejection could be overcome by amending the claim to recite "said exposing step."

Claim 14 recites the limitation "the CYP2D6 gene" in the second and third line of the claim. There is insufficient antecedent basis for this limitation in the claim, because claim 11 does not employ the terminology "CYP2D6 gene."

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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12. Claims 11, 13-14, and 16 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cronin et al (U.S. 6,468,744 B1 [10/22/2002; requirements of 35 USC 371(c)(1)(2) and (4) fulfilled 11/17/1999]).

Cronin et al disclose methods of genotyping CYP2D6 that comprise the simultaneous detection of the copy number of multiple forms of the gene (including multiple polymorphic forms) in a sample; the method of Cronin et al comprises providing a sample and an array configured in such a way so as to detect both copy number and polymorphic forms of CYP2D6, and also comprises exposing the sample to the array so as to detect CYP2D6 genotype (see entire reference, particularly column 2, line 45-column 4, line 50; column 27, line 1-column 29 [including Tables 3-4]); column 35, lines 35-59; column 37, line 18-column 39, line 5; column 40, line 11-column 42, line 12; Figures 10-11). With further regard to claim 13, it is noted that Cronin et al disclose target amplification prior to assay exposure (see, e.g., column 26, lines 35-58, particularly lines 57-55). With further regard to claim 14, as the assay of Cronin et al detects both CYP2D6 gene copy number and copy numbers of multiple portions of CYP2D6 genes (including polymorphic sequences), the assay of Cronin et al meets the limitations of the claim. Accordingly, Cronin et al clearly anticipate instant claims 11, 13-14, and 16.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cronin et al (U.S. 6,468,744 B1 [10/22/2002; requirements of 35 USC 371(c)(1)(2) and (4) fulfilled 11/17/1999]) in view of Mein et al (Genome Research 10(3):330-343 [3/2000]).

Cronin et al disclose array-based methods of genotyping CYP2D6 that comprise the simultaneous detection of the copy number of multiple forms of the gene (including multiple polymorphic forms) in a sample; the method of Cronin et al comprises providing a sample and an array configured in such a way so as to detect both copy number and polymorphic forms of CYP2D6, and also comprises exposing the sample to the array so as to detect CYP2D6 genotype (see entire reference, particularly column 2, line 45-column 4, line 50; column 27, line 1-column 29 [including Tables 3-4]); column 35, lines 35-59; column 37, line 18-column 39, line 5; column 40, line 11-column 42, line 12; Figures 10-11). Cronin et al do not disclose a detection assay that "comprises an invasive cleavage assay," as required by claim 12. Mein et al disclose the existence of

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a variety of assays for genotyping, including both microarray based assays, and Invader assays (see entire reference, particularly pages 330 and 331, left column). Mein et al disclose the successful use of PCR-Invader assays in the high-throughput typing of numerous SNPs (see entire reference, particularly pages 338 and 340), and teach that their finding support numerous advantages of the PCR-Invader assay in high throughput genotyping, including its microtitre format, the need for only a single addition of reagents, the generation of a stable fluorescent signal, "simple data interpretation," a reduced error rate, simplicity of assay design and optimization, relatively low cost, and "flexibility and robustness" (see page 340). In view of the teachings of Mein et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Cronin et al so as to have either modified Cronin et al's assay to achieve detection of polymorphic sequences and copy number using the PCR-Invader assay taught by Mein et al, or so as to have additionally performed detection of polymorphic sequences and copy number using the PCR-Invader assay taught by Mein et al. An ordinary artisan would have been motivated to have made such a modification so as to have achieved any or all of the above-listed advantages taught by Mein et al.

### ***Double Patenting***

16. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

17. Claims 11-14 and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 11-14 and 16 of copending Application No.

10/956,507. Claims 11-14 and 16 of the instant application are identical to claims 11-14 and 16, respectively, of the '507 application. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 11-14 and 16 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15 and 17 of copending Application No. 10/956,507. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11-14 and

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16 of the instant application are generic to all that is recited in claims 15 and 17 of the '507 application. That is, claims 15 and 17 of the '507 patent fall entirely within the scope of instant claims 11-14 and 16, or, in other words, instant claims 11-14 and 16 are anticipated by claims 15 and 17 of the '507 patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

20. The art made of record and not relied upon is considered pertinent to applicant's disclosure. It is noted that data disclosed in provisional application 60/371,819 (filed 04/11/2002) appears to be disclosed in the later published reference of Neville et al (BioTechniques 32:S34-S43 [6/2002]).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Diana B. Johannsen  
Primary Examiner  
Art Unit 1634